

REMARKS

Initially, Applicants would like to express appreciation to the Examiner for the detailed Official Action provided, for the acknowledgment of Applicants' Claim for Priority and receipt of the certified copy of the priority document, and for the acknowledgment of Applicants' Information Disclosure Statements by return of the Forms PTO-1449.

Upon entry of the above amendment, claims 1, 7, and 14-17 will have been amended. Accordingly, claims 1-17 are currently pending. Applicants respectfully request reconsideration of the outstanding rejections and allowance of claims 1-17 in the present application. Such action is respectfully requested and is now believed to be appropriate and proper.

Claims 1, 2, 4-7, and 13-17 have been rejected under 35 U.S.C. § 102(b) as being anticipated by LIPKOVER (U.S. Patent No. 5,421,816).

Although Applicants do not necessarily agree with the Examiner's rejection of the claims on this ground, nevertheless, Applicants have amended independent claims 1, 7, and 14-17 to clearly obviate the above noted ground of rejection in order to expedite prosecution of the present application. In this regard, Applicants note that LIPKOVER fails to show each and every element recited in the amended claims. In particular, claim 1, as amended, sets forth an ultrasonic percutaneous penetration device including, inter alia, "an irradiation unit that applies ultrasonic waves having a frequency of not less than 0.5 MHz from skin or a surface capable of contacting the medicine, said irradiation unit including a first ultrasonic transducer that generates ultrasonic waves at a first frequency and a second ultrasonic transducer that generates ultrasonic waves at a second frequency different from the first frequency; and a control unit that controls irradiation conditions of the irradiation unit, said control unit controlling said first and second ultrasonic transducers to generate ultrasonic waves at said different frequencies simultaneously

and serially". Claim 7, as amended, sets forth an ultrasonic percutaneous penetration kit including, inter alia, "a medicine containing an active ingredient; an irradiation unit that applies ultrasonic waves having a frequency of not less than 0.5 MHz from a surface capable of contacting the medicine, said irradiation unit including a first ultrasonic transducer that generates ultrasonic waves at a first frequency and a second ultrasonic transducer that generates ultrasonic waves at a second frequency different from the first frequency; and a control unit that controls irradiation conditions of the irradiation unit, said control unit controlling said first and second ultrasonic transducers to generate ultrasonic waves at said different frequencies simultaneously and serially". Claims 14-17, as amended, each set forth an ultrasonic percutaneous penetration method including, inter alia, contacting a skin surface with a medicine, and applying ultrasonic waves, "said applying ultrasonic waves comprises providing an irradiation unit including a first transducer that generates ultrasonic waves at a first frequency and a second ultrasonic transducer that generates ultrasonic waves at a second frequency different from the first frequency, and providing a control unit that controls irradiation conditions of the irradiation unit, said control unit controlling said first and second ultrasonic transducers to generate ultrasonic waves at said different frequencies simultaneously and serially".

This amendment is fully supported by the specification, including the claims and drawings, and no prohibited new matter has been added. In particular, support for the above noted amendments may be found at least in figure 4 and in the specification on page 16, line 8 through page 18, line 20.

Applicants' claimed invention includes an ultrasonic percutaneous penetration device and method including an irradiation unit with a first transducer that generates ultrasonic waves at a first frequency and a second transducer that generates ultrasonic waves at a second frequency

that is different from the first frequency, and a control unit that controls irradiation conditions of the irradiation unit. The control unit controls the first and second ultrasonic transducers so that ultrasonic waves may be generated at different frequencies either simultaneously or serially.

Accordingly, the two ultrasonic transducers 20 and 21 may be operated individually or alternately, depending on the application, the portions to be used, or the irradiation conditions. This configuration of Applicants' invention provides that ultrasonic waves may be simultaneously applied to two or more portions of the organism 2, or two or more kinds of ultrasonic waves having different conditions may be applied alternately.

Additionally, the ultrasonic percutaneous penetration device and method of the present invention may be provided with a control unit 3 and an irradiation unit 4 that can generate two or more ultrasonic waves having different frequencies. For example, when two ultrasonic waves having different frequencies are generated, the ultrasonic percutaneous penetration device of figure 4 includes the control unit 3 controlling the operation so that the frequency of an ultrasonic wave generated by the ultrasonic transducer 20 and applied to the skin surface 2a is different from the frequency of an ultrasonic wave generated by the ultrasonic transducer 21 and applied to the skin surface 2a. In the case when these two ultrasonic waves having different frequencies are generated, an ultrasonic wave having a frequency of approximately 1 MHz (0.5 to 2 MHz) that is a frequency of a comparatively low band is generated by one of the ultrasonic transducers 20 while, an ultrasonic wave having a frequency of approximately 2 MHz or more that is a frequency of a comparatively high band is generated by the other ultrasonic vibrator 20. Accordingly, ultrasonic waves having two different frequencies may be combined, and simultaneously applied to the skin surface 2a. Moreover, the ultrasonic percutaneous penetration device of the present invention may be switched so as to apply two or more ultrasonic waves

having different frequencies, and can also apply two or more ultrasonic waves having different frequencies simultaneously or in succession. Thus, by generating two or more ultrasonic waves having different frequencies and by simultaneously applying these two ultrasonic waves to the skin surface 2a in combination, two or more different functions, exerted by two or more ultrasonic waves having different frequencies, are combined together, and applied to the organism 2. Therefore, the penetrating properties of the medicine 1 to the organism 2 is improved by the irradiation unit and control unit of Applicants' present invention. See particularly pages 16-18 of the specification.

The LIPKOVER patent discloses an ultrasonic transdermal delivery system including an irradiation unit that applies ultrasonic waves, and a control unit that controls irradiation conditions. The LIPKOVER patent discloses that the device applies ultrasonic stimuli by energizing the stimuli transducer at a first frequency, and applies variable frequency ultrasonic pulses (column 5, lines 23-32). However, the LIPKOVER device includes *only a single transducer*. Thus, the LIPKOVER device does not include a first ultrasonic transducer that generates ultrasonic waves at a first frequency and second ultrasonic transducer that generates ultrasonic waves at a second frequency different from the first frequency. Since the LIPKOVER device includes *only a single transducer*, the LIPKOVER device also cannot operate such that ultrasonic waves of different frequencies are generated simultaneously. Therefore, the LIPKOVER device does not include a control unit that controls a first transducer and a second transducer to generate ultrasonic waves at different frequencies simultaneously and serially. Thus, the LIPKOVER patent does not show an ultrasonic percutaneous penetration device and method including, *inter alia*, an irradiation unit, "said irradiation unit including a first ultrasonic transducer that generates ultrasonic waves at a first frequency and a second ultrasonic transducer

that generates ultrasonic waves at a second frequency different from the first frequency; and a control unit that controls irradiation conditions of the irradiation unit, said control unit controlling said first and second ultrasonic transducers to generate ultrasonic waves at said different frequencies simultaneously and serially”, as set forth in amended claims 1 and 7; and providing ultrasonic waves, “said applying ultrasonic waves comprises providing an irradiation unit including a first transducer that generates ultrasonic waves at a first frequency and a second ultrasonic transducer that generates ultrasonic waves at a second frequency different from the first frequency, and providing a control unit that controls irradiation conditions of the irradiation unit, said control unit controlling said first and second ultrasonic transducers to generate ultrasonic waves at said different frequencies simultaneously and serially”, as set forth in amended claims 14-17.

Since the reference fails to show each and every element of the claimed device, the rejection of claims 1, 7, and 14-17 under 35 U.S.C. § 102(b) over LIPKOVER is improper and withdrawal thereof is respectfully requested.

Applicants submit that dependent claims 2-6 and 8-13, which are at least patentable due to their dependency from claims 1 and 7 for the reasons noted above, recite additional features of the invention and are also separately patentable over the prior art of record based on the additionally recited features.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections, and an early indication of the allowance of claims 1-17.

SUMMARY AND CONCLUSION

In view of the foregoing, it is submitted that the present amendment is proper and that none of the references of record, considered alone or in any proper combination thereof, anticipate or render obvious Applicants' invention as recited in claims 1-17. The applied references of record have been discussed and distinguished, while significant claimed features of the present invention have been pointed out.

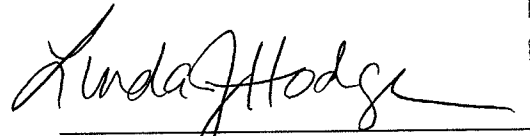
Accordingly, consideration of the present amendment, reconsideration of the outstanding Official Action, and allowance of the present amendment and all of the claims therein are respectfully requested and now believed to be appropriate.

Applicants have made a sincere effort to place the present application in condition for allowance and believe that they have now done so.

Any amendments to the claims which have been made in this amendment, which do not narrow the scope of the claims, and which have not been specifically noted to overcome a rejection based upon the prior art, should be considered cosmetic in nature, and to have been made for a purpose unrelated to patentability, and no estoppel should be deemed to attach thereto.

Should the Examiner have any questions, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully Submitted,
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A handwritten signature in black ink, appearing to read "Linda J. Hodge", written over a horizontal line.

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